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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/811,762

03/19/2001

Virginia Goss Tusher

M-10523 US

8102

36257

7590

10/20/2004

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EXAMINER

MARSCHER, ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/811,762	TUSHER ET AL.	
	Examiner	Art Unit	
	Ardin Marschel	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 23-27,31,32,34-43,45,47-57,59, & 61-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22,28-30,33,44,46,58 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-64 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>(2 copies)</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Applicant's election without traverse of Group I, Specie A (identification practice of genes via statistical significance without requiring additionally the identification of falsely identified values as generically described in claim 1, for example); Specie C (identification practice of genes wherein there is no required transmitting of a program of instructions to a client, e.g., as in instant claim 54) in the reply filed on 8/3/04 is acknowledged. Claims 1-22, 28-30, 33, 44, 46, 58, and 60 are under examination as a result of the above elections.

VAGUENESS AND INDEFINITENESS

Claims 1-22, 28-30, 33, 44, 46, 58, and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 1-4, cite the obtaining of data from a number of data sources. Lines 5-13, lack any plurality of data source limitation. Thus, the claim is vague and indefinite as to whether the preamble or the actual claim steps control the metes and bounds as they are different. Independent claims 28, 44, 46, 58, and 60 also contain this unclarity. Clarification via clearer claim wording is requested. Claims which depend directly or indirectly from an independent claim as listed above also contain this unclarity due to their dependence.

NON-STATUTORY SUBJECT MATTER

Claims 1-22, 28-30, 33, 44, 46, 58, and 60 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Consideration of the "Computer-Related Inventions" section of the MPEP at section 2106, Part IV, subpart B, has revealed that the instant claims are directed to non-statutory subject matter without requiring performance of a result outside of a computer. Thus, the manipulation of data or conversion of data, in this case gene data is the claimed subject matter without any physical transformation outside of a computer. For example, it is well known that a software program may output results to a computer file and not display it, for example, outside of the computer. The above instant claims also lack statutory subject matter due to being directed to nonfunctional descriptive material since the claims lack performance or control of a physical transformation. The presence of such nonfunctional descriptive material on a computer medium or in a computer system does not prevent this rejection because such nonfunctional descriptive material lacks the implementation of physical functionality regarding such computer elements. Additionally, applicant(s) may wish to argue that the methods are directed to a practical utility. Consideration of the MPEP at section 2106, Part IV, subpart B, sub-subpart 2, reveals that such practical utility requires the production of a useful, concrete, and tangible result which is reasonably interpreted as at least some physicality of result as required for statutory subject matter. Methods per se as instantly claimed subject matter is reasonably deemed a manipulation of data for such methods, without any physicality, that is, concrete or tangible, requirement. It is noted that the practical utility requirement is directed to a required combination of a useful, concrete, and tangible result which supports this rejection if only one or more of these criteria fail to be met in the claimed subject matter.

LACK OF UTILITY

The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

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Claims 1-22, 28-30, 33, 44, 46, 58, and 60 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

Applicant should explicitly identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 1-22, 28-30, 33, 44, 46, 58, and 60 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-7, 16, 28, 58, and 60 are rejected under 35 U.S.C. 102(a) and (e)(2) as being clearly anticipated by Amerson et al. (P/N 5,908,978).

Amerson et al. is directed to methods of family selection via genetic markers as summarized in the title and abstract. The abstract also summarizes the quantification of traits in breeding plants and family trees. Such traits or values are further summarized in column 12, line 33, through column 14, line 45. Column 14, line 46, discloses the selection of individuals carrying genes for desirable traits which is a disclosure of gene difference information as instantly claimed. Statistical significance is evaluated as summarized in column 16, line 39, through column 17, line 28, as also instantly claimed. Averaging to adjust values to make adjusted values substantially independent of scatter as instantly claimed in claim 1, lines 7-9, is disclosed in the reference in column 30, line 34, through column 31, line 4. The identification of genes with desired traits as noted above regarding differing values also anticipates the last 2 lines of instant claim 1.

Thus, the reference anticipates the above listed instant claims.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is

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(571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

October 15, 2004

J. L. Woodward
10/15/04